

Form PTO-1449

Docket Number 252312007400

Application Number 09/724,822

**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**

(Use several sheets if necessary)

Applicant

Matthew D. LINNIK and Patricia A. McNEELY

Filing Date November 28, 2000

Group Art Unit 1636

Mailing Date July 10, 2003

**U.S. PATENT DOCUMENTS**

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
CQ	1.	08/02/2001	2001/0010808	Yagi et al.			
	2.	08/01/2002	2002/0103343	Taylor et al.			
	3.	12/12/2002	2002/0187156	Dintizis et al.			
	4.	04/24/2003	2003/0077273	Linnik et al.			
	5.	06/09/1998	60/088,656	Marquis et al.			
	6.	10/05/1998	60/103,088	Marquis et al.			
	7.	12/09/1998	60/111,641	Jones			
	8.	06/08/1999	60/138,260	Jones et al.			
	9.	06/08/1999	09/328,199	Marquis et al.			
	10.	06/08/2000	09/590,592	Jones et al.			
	11.	06/07/2001	09/877,387	Jones			
	12.	02/23/1999	5,874,552	Jones et al.			
	13.	01/22/2002	6,340,460	Dintzis			
	14.	04/23/2002	6,375,951	Dintzis			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
CQ	15.	07/25/1991	WO 91/10426	WIPO			
	16.	06/14/2001	WO 01/41813	WIPO			
	17.	12/13/2001	WO 01/93914	WIPO			
	18.	11/21/2002	WO 02/092011	WIPO			

**OTHER DOCUMENTS** (including author, title, Date, Pertinent Pages, Etc.)

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| 19. | Alarcon-Segovia, D. et al. (2000). SL1 Trial Shows Fewer Renal Flares in LJP 394-Treated Patients with High-Affinity Antibodies to LJP 394:90-05 Trial Results," <i>Arth. Rheumat.</i> 43(9 supplement):S272 (abstract 1231).     |
| 20. | Furie, R.A. et al. (2001). "Treatment of Systemic Lupus Erythematosus with LJP 394," <i>J. Rheumatol.</i> 28:257-265.   |
| 21. | Henderson, A.L. et al. (2002). "Concerted Clearance of Immune Complexes Bound to the Human Erythrocyte Complement Receptor: Development of a Heterologous Mouse Model," <i>J Immunol Methods.</i> 270(2):183-97.                  |
| 22. | Lindorfer, M.A. et al. (2001). "A Bispecific dsDNAxmonoclonal Antibody Construct for Clearance of Anti-dsDNA IgG in Systemic Lupus Erythematosus," <i>J. Immunol. Methods</i> 248(1-2):125-138.                                   |
| 23. | Linnik, M.D. and Bagin, R.G. (2000). "Effect of LJP 394 on Patients with Greatest Impairment of Renal Function at Baseline in the 90-05 Trial," <i>Arth. Rheumat.</i> 43(9 supplement):S241 (abstract 1046).                      |
| 24. | Linnik, M.D. et al. (2000). "Affinity of Antibodies for LJP 394 Influences Pharmacodynamic Response to LJP 394 in SLE Patients with Positive dsDNA Antibody Titers," <i>Arth. Rheumat.</i> 43(9 supplement):S241 (abstract 1045). |
| 25. | Pistiner, M. et al. (1991). "Lupus Erythematosus in the 1980s: A Survey of 570 Patients," <i>Semin. Arthritis Rehum.</i> 21(1):55-64.   |
| 26. | Strand, V. (2001). "Monoclonal Antibodies and Other Biologic Therapies," <i>Lupus</i> 10:216-221.   |
| 27. | Wallace, D.J. (2001). "Clinical and Pharmacological Experience with LJP-394," <i>Expert Opinion of Investigational Drugs</i> 10(1):111-117.   |

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## U.S. PATENT DOCUMENTS

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CQ	1.	08/02/2001	2001/0010818	Engle et al.			
	2.	06/19/2003	2003/0114405	Linnik et al.			
	3.	12/07/1993	5,268,454	Barstad et al.			
	4.	10/06/1998	5,817,752	Yu			
	5.	01/05/1999	5,856,464	Livingston			

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
CA	6.	12/19/1996	WO 96/40708	WIPO			
V	7.	12/11/1997	WO 97/46248	WIPO			

## OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)

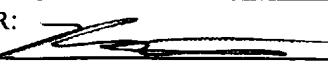
Examiner Initials	Ref. No.	
CQ	8.	Alarcon-Segovia, D. et al. (2001). "SLE Trial Shows Fewer Renal Flares in LJP 394-Treated Patients with High-Affinity Antibodies to LJP 394:90-05 Trial Results," located at < <a href="http://www.ljpc.com/abstracts/abstract_2001_02.html">http://www.ljpc.com/abstracts/abstract_2001_02.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.
	9.	Alarcon-Segovia, D. et al. (2003). "LJP 394 for the Prevention of Renal Flare in Patients with Systemic Lupus Erythematosus: Results from a Randomized, Double-Blind, Placebo-Controlled Study," located at < <a href="http://www.ljpc.com/abstracts/abstract_2003_01.html">http://www.ljpc.com/abstracts/abstract_2003_01.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.
	10.	Alarcon-Segovia, D. et al. (2003). "SLE Trial Shows Fewer Renal Flares in LJP 394-Treated Patients with High-Affinity Antibodies to LJP 394:90-05 Trial Results," located at < <a href="http://www.ljpc.com/abstracts/abstract_2000_sle_trial.html">http://www.ljpc.com/abstracts/abstract_2000_sle_trial.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.
	11.	Alarcon-Segovia, D. et al. "SLE Trial Shows Fewer Renal Flares in LJP-394 Treated Patients with High-Affinity Antibodies to LJP-394: 90-05. Trial Results," <i>Lupus</i> 10 (Supplement 1):pS272: 1231.

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		Filing Date November 28, 2000	Group Art Unit 1636
		Mailing Date February 13, 2004	
CQ	12.	Cardiel, M. (2003). "Randomized, Placebo Controlled, Double-Blind Phase III Clinical Trial for the Evaluation of LJP 394 (Abetimus Sodium) in the Treatment of Patients with SLE who are at Risk for Renal Flare," located at < <a href="http://www.ljpc.com/abstracts/abstract_2003_02.html">http://www.ljpc.com/abstracts/abstract_2003_02.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.	
	13.	Cardiel, M.H. et al. (2003). "Clinical Efficacy Results from a RCT of LJP 394 in SLE Patients with History of Renal Disease," <i>Arthritis and Rheumatism</i> 48(9):582-583.	
	14.	Cardiel, M.H. et al. (2003). "Clinical Efficacy Results from a RCT of LJP 394 in SLE Patients with History of Renal Disease," located at < <a href="http://www.ljpc.com/abstracts/abstract_2003_07.html">http://www.ljpc.com/abstracts/abstract_2003_07.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.	
	15.	Furie, R.A. et al. (2000). "Treatment of Systemic Lupus Erythematosus with LJP 394," located at < <a href="http://www.ljpc.com/abstracts/abstract_2001_16.html">http://www.ljpc.com/abstracts/abstract_2001_16.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.	
	16.	Iverson et al. (1998) "A Chemically Defined, Toleragen-Based Approach for Targeting Anti- $\beta_2$ -glycoprotein I Antibodies" <i>Lupus</i> 7 (Suppl 2): S166-S169.	
	17.	Iverson et al. (1998) "Anti- $\beta_2$ glycoprotein I ( $\beta_2$ GPI) Autoantibodies Recognize an Epitope on the First Domain of $\beta_2$ GPI" <i>Proc Natl Acad Sci USA</i> 95:15542-15546.	
	18.	Jones et al. (1998) "Synthesis of a Cyclic-Thioether Peptide which Binds Anti-Cardiolipin Antibodies" <i>Tetrahedron Letters</i> 39:6107-6110.	
	19.	Jones, D. (1991). "Case Study: Lupus Nephritis," <i>American Nephrology Nurses' Association</i> 18(3):327-329.	
	20.	Jones, D. (1994). "A New Oligonucleotide Conjugate for Suppression of Anti-Double Stranded DNA Antibodies," <i>Abstracts of Papers American Chemical Society</i> 207(1-2):pBIOT 113.	
	21.	Kandiah et al. (1998) "Current Insights into the "Antiphospholipid" Syndrome: Clinical, Immunological, and Molecular Aspects" <i>Advances in Immunology</i> 70:507-563.	
	22.	La Jolla Pharmaceutical Co. Press Release. (March 31, 2003). "Results from Two Riquent <sup>TM</sup> Trials Show Lupus Patients with Sustained Reductions in Antibodies to dsDNA Have Fewer Renal Flares," San Diego, CA. 4 pages.	
	23.	Linnik, M.D. et al. (2000). "Affinity of Antibodies for LJP 394 Influences Pharmacodynamic Response to LJP 394 in SLE Patients with Positive dsDNA Antibody Titers," <i>Arthritis and Rheumatism</i> 43(9):1045.	
	24.	Linnik, M.D. et al. (2000). "Affinity of Antibodies for LJP 394 Influences Pharmacodynamic Response to LJP 394 in SLE Patients with Positive dsDNA Antibody Titers," located at < <a href="http://www.ljpc.com/abstracts/abstract_2000_affinity.html">http://www.ljpc.com/abstracts/abstract_2000_affinity.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.	
	25.	Linnik, M.D. et al. (2000). "Effect of LJP 394 on Patients with Greatest Impairment of Renal Function at Baseline in the 90-05 Trial," <i>Arthritis and Rheumatism</i> 43(9):1046.	
	26.	Linnik, M.D. et al. (2000). "Effect of LJP 394 on Patients with Greatest Impairment of Renal Function at Baseline in the 90-05 Trial," located at < <a href="http://www.ljpc.com/abstracts/abstract_2000_effect.html">http://www.ljpc.com/abstracts/abstract_2000_effect.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.	
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27. Linnik, M.D. et al. (2000). "Reduction in Anti-dsDNA Antibodies by LJP 394 in Lupus Patients is Influenced by Affinity for the LJP 394 dsDNA Eptiope," located at <[http://www.ljpc.com/abstracts/abstract\\_2000\\_reduction.html](http://www.ljpc.com/abstracts/abstract_2000_reduction.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.
28. Linnik, M.D. et al. (2001). "Affinity of Antibodies for LJP 394 Influences Pharmacodynamic Response to LJP 394 in SLE Patients," located at <[http://www.ljpc.com/abstracts/abstract\\_2001\\_04.html](http://www.ljpc.com/abstracts/abstract_2001_04.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.
29. Linnik, M.D. et al. (2001). "Affinity of Antibodies for LJP 394 Influences Pharmacodynamic Response to LJP 394 in SLE Patients," *Lupus* 10(Supplement 1):pS52:30.
30. Linnik, M.D. et al. (2001). "Effect of LJP 394 on SLE Patients with Impaired Renal Function," located at <[http://www.ljpc.com/abstracts/abstract\\_2001\\_03.html](http://www.ljpc.com/abstracts/abstract_2001_03.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.
31. Linnik, M.D. et al. (2001). "Effect of LJP 394 on SLE Patients with Impaired Renal Function," *Lupus* 10(Supplement 1):pS17:19.
32. Linnik, M.D. et al. (2001). "Effect of LJP 394 or High Dose Corticosteroids and Cyclophosphamide on Anti-dsDNA Antibodies in SLE Patients," located at <[http://www.ljpc.com/abstracts/abstract\\_2001\\_09.html](http://www.ljpc.com/abstracts/abstract_2001_09.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.
33. Linnik, M.D. et al. (2001). "Effect of LJP or High Dose Corticosteroids and Cyclophosphamide on Anti-dsDNA Antibodies in SLE Patients," *Arthritis and Rheumatism* 44(9):S282:1378.
34. Linnik, M.D. et al. (2002). "Workshop Report on Some New Ideas About the Treatment of Systemic Lupus Erythematosus" *Lupus* 11:793-796.
35. Linnik, M.D. et al. (2002). "Effect of LJP 394 or High Dose Corticosteroids and Cyclophosphamide on Anti-dsDNA Antibodies in SLE Patients," located at <[http://www.ljpc.com/abstracts/abstract\\_2002\\_05.html](http://www.ljpc.com/abstracts/abstract_2002_05.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.
36. Linnik, M.D. et al. (2002). "Effect of LJP 394, High Dose Corticosteroids and Cyclophosphamide (HDCC) on Anti-dsDNA Antibodies in SLE Patients," located at <[http://www.ljpc.com/abstracts/abstract\\_2002\\_02.html](http://www.ljpc.com/abstracts/abstract_2002_02.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.
37. Linnik, M.D. et al. (2002). "Reduction in Antibodies to dsDNA Using LJP in Dose Ranging Trial in Lupus Patients," located at <[http://www.ljpc.com/abstracts/abstract\\_2002\\_01.html](http://www.ljpc.com/abstracts/abstract_2002_01.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.
38. Linnik, M.D. et al. (2002). "Workshop Report on Some New Ideas about the Treatment of Systemic Lupus Erythematosus," located at <[http://www.ljpc.com/abstracts/abstract\\_2002\\_10.html](http://www.ljpc.com/abstracts/abstract_2002_10.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.
39. Linnik, M.D. et al. (2003). "Reductions in Anti-DSDNA Antibodies and Reduced Risk of SLE Renal Flare and Major SLE Flare," located at <[http://www.ljpc.com/abstracts/abstract\\_2003\\_09.html](http://www.ljpc.com/abstracts/abstract_2003_09.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.

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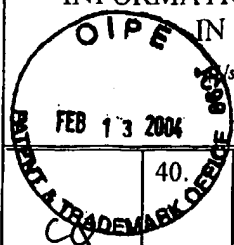
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| 40. | Linnik, M.D. et al. (2003). "SLE Patients with Sustained Reductions in Anti-DSDNA Antibodies Have a Reduced Risk of Renal Flare and Major SLE Flare," located at < <a href="http://www.ljpc.com/abstracts/abstract_2003_05.html">http://www.ljpc.com/abstracts/abstract_2003_05.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.                             |
| 41. | McNeeley, P.A. et al. (2000). "Lupus Patient Pharmacodynamic Response to LJP 394 is Influenced by Pre-Treatment Antibody Affinity for LJP 394," located at < <a href="http://www.ljpc.com/abstracts/abstract_2000_pharmaco_response.html">http://www.ljpc.com/abstracts/abstract_2000_pharmaco_response.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.     |
| 42. | McNeeley, P.A. et al. (2001). "Pre-Treatment Affinity for LJP 394 Influences Pharmacodynamic Response in Lupus Patients," located at < <a href="http://www.ljpc.com/abstracts/abstract_2001_13.html">http://www.ljpc.com/abstracts/abstract_2001_13.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.  |
| 43. | Morimoto, C. et al. (1982). "Correlation Between Clinical Activity of Systemic Lupus Erythematosus and the Amounts of DNA in DNA/Anti-DNA Antibody Immune Complexes," <i>J. Immunol.</i> 139(5):1960-1965.  |
| 44. | Morimoto, C. et al. (1987). "A Defect of Immunoregulatory T Cell Subsets in Systemic Lupus Erythematosus Patients Demonstrated with Anti-2H4 Antibody," <i>J Clin Invest.</i> 79(3):762-768.  |
| 45. | Saffran, D.C. et al. (2002). "Treatment of Antibody-Mediated SLE-Like Disease in Male BXSB Mice with a B-Cell Toleragen Specific for Anti-dsDNA Antibodies," located at < <a href="http://www.ljpc.com/abstracts/abstract_2002_04.html">http://www.ljpc.com/abstracts/abstract_2002_04.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 1 page.                       |
| 46. | Sem, D.S. et al. (1998). "Structural Characterization and Optimization of Anti-body Selected Phage Library Mimotopes of an Antigen Associated with Autoimmune Recurrent Thrombosis," <i>Biochemistry</i> 37(46):16069-16091.  |
| 47. | Tumlin, J.A. et al. (2001). "The B-Cell Toleragen LJP-394 Reduces Renal Flares in Patients with Lupus Nephritis: A Prospective Double-Blinded, Placebo Controlled Trial," located at < <a href="http://www.ljpc.com/abstracts/abstract_2001_08.html">http://www.ljpc.com/abstracts/abstract_2001_08.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.         |
| 48. | Tumlin, J.A. et al. (2001). "The B-Cell Toleragen LJP-394 Reduces Renal Flares in Patients with Lupus Nephritis: A Prospective, Double-Blinded, Placebo Controlled Trial," <i>Journal of the American Society of Nephrology</i> 12:p253A.   |
| 49. | Tumlin, J.A. et al. (2003). "Efficacy Results from a RCT of LJP 394 in SLE Patients with History of Renal Disease," located at < <a href="http://www.ljpc.com/abstracts/abstract_2003_10.html">http://www.ljpc.com/abstracts/abstract_2003_10.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.   |
| 50. | Tumlin, J.A. et al. (2003). "Renal Flare in SLE Patients with Impaired Renal Function in a RCT of LJP 394," located at < <a href="http://www.ljpc.com/abstracts/abstract_2003_12.html">http://www.ljpc.com/abstracts/abstract_2003_12.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.   |
| 51. | Wallace, D.J. et al. (2003). "Safety Results from a Randomized Controlled Trial (RCT) of LJP 394 in Systemic Lupus Erythematosus (SLE) Patients with a History of Renal Disease," located at < <a href="http://www.ljpc.com/abstracts/abstract_2003_06.html">http://www.ljpc.com/abstracts/abstract_2003_06.html</a> > visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages. |

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Wallace, D.J. et al. (2003). "Safety Results from a RCT of LJP 394 in SLE Patients with a History of Renal Disease," located at <[http://www.ljpc.com/abstracts/abstract\\_2003\\_11.html](http://www.ljpc.com/abstracts/abstract_2003_11.html)> visited on December 8, 2003. La Jolla Pharmaceutical Co. Abstracts. 2 pages.

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